Message

From: Flowers, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4411C874D041B9A8BADFC32B91BD70-FLOWERS, LYNN]
Sent: 8/13/2013 5:32:44 PM
To: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Walsh, Debra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4fd965338fc4d449c2954945c41de46-Walsh, Debra]
Subject: RE: NEWS UPDATES: EPA Public Meetings Indicate Restart Of Controversial IRIS Assessments (Risk Policy Report)

Kacee et al:
Three points---

Deliberative Process / Ex. 5

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From: Deener, Kathleen
Sent: Tuesday, August 13, 2013 12:50 PM
To: Cogliano, Vincent; Flowers, Lynn; Vandenberg, John; Walsh, Debra

Subject: FW: NEWS UPDATES: EPA Public Meetings Indicate Restart Of Controversial IRIS Assessments (Risk Policy Report)

Do you think we should ask Maria for a correction for this story? In her story, she says that "EPA announced last year that it would not use Ramazzini cancer data in the ongoing IRIS assessments of methanol and the fuel additives methyl tertiary butyl ether (MTBE) and ETBE, suggesting re-writes of those documents would be necessary." She then goes on to say that, for ETBE, "the evidence tables for cancer include one of the Ramazzini studies by Maltoni et al., published in the *European Journal of Oncology* in 1999."

As you know, what we actually said about Ramazzini was that we would not use RI data on lymphomas and luekemias and that this decision would affect the assessments for methanol, MTBE and ETBE. We said we would continue to consider RI solid tumor data in IRIS assessments. I'm assuming the RI study in the ETBE evidence table was solid tumor data (if my assumption is wrong, we have a different problem!).

Let me know what you think about asking for a correction/clarification.

Kacee Deener, MPH
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From: Deener, Kathleen
Sent: Tuesday, August 13, 2013 9:40 AM
To: Alexander, Laurie; Avery, James; Ball, James; Barone, Stan; Bateson, Thomas; Berner, Ted; Birchfield, Norman; Blessinger, Todd; Bonanni, Christina; Boone-Edwards, Amanda; Brinkerhoff, Chris; Buckley, Barbara; Burgoon, Lyle; Bussard, David; Cai, Christine; Caldwell, Jane; Carmichael, Brenda; Chiu, Weihsueh; Choudhury, Harlal; Christensen, Krista; Corona, Elizabeth; Cote, Ila; Cubbison, Christopher; CURTIS, LUCY; Davis, Allen; Deener, Kathleen; Erwin, Elizabeth; Evans, Amanda; Field, Malcolm; Flowers, Lynn; Frederick, Bob; Frithsen, Jeff; Galizia, Audrey; Gamble, Janet; Gatchett, Annette; Gehlhaus, Martin; Gibbons, Catherine; Gillespie, Patricia; Glenn, Barbara; Grambsch, Anne; Guyton, Kate; Gwinn, Maureen; Hammerstrom, Karen; Hawkins, Belinda; Hogan, Karen; Hotchkiss, Andrew; Jarabek, Annie; Jinot, Jennifer; Johnson, Maureen; Jones, Samantha; Kadry, Abdel-Razak; Kaiser, Jonathan; Keshava, Nagalakshmi; Knecht, Helen; Kopylev, Leonid; Kraft, Andrew; Lee, Janice; Lehmann, Geniece; Long, Tom; D'Amico, Louis; Luke, April; Makris, Susan; Marcus, Allan; McLanahan, Eva; Moore, Danielle; Murphy, Patricia; Newhouse, Kathleen; Olden, Kenneth; Perovich, Gina; Persad, Amanda; Petersen, Dan; Powers, Christina; Pratt, Margaret; Preuss, Peter; Raffaele, Kathleen; Reid, Jon; Rieth, Susan; Ris, Charles; Ross, Christine; Ross, Mary; Rutigliano, Marian; Salazar, Keith; Sams, Reeder; Sanchez, Yolanda; Sasso, Alan; Schlosser, Paul; Scott, Cheryl; Segal, Deborah; Serfling, Kelly; Shaw, Denice; Sheth, Christopher; Slimak, Michael; Sonawane, Bob; Spassova, Maria; Spyropoulos, Stella; Strong, Jamie; Subramaniam, Ravi; Suter, Glenn; Troyer, Michael; Vandenberg, John; Vinikoor-Imler, Lisa; Vulimiri, Suryanarayana; Walker, Teneille; Walsh, Debra; Wang, Nina; White, Paul; Woodall, George; Wright, Barbara; Wright, Michael; Yang, Hui Min; Zwayer, Bette; Itkin, Cheryl; DeSantis, Joe
Subject: NEWS UPDATES: EPA Public Meetings Indicate Restart Of Controversial IRIS Assessments (Risk Policy Report)

EPA Public Meetings Indicate Restart Of Controversial IRIS Assessments

Posted: August 12, 2013

EPA appears to be restarting the Integrated Risk Information System (IRIS) assessment process for two long-controversial chemicals and has announced a series of public meetings to discuss the early stages of these assessments as part of the agency's recent revisions to its process for developing the influential toxicity assessments.

Industry and other stakeholders have long sought earlier access to the process of developing the IRIS assessments that often guide EPA's regulatory decision-making but take program staff years to complete. The newest IRIS process document indicates that average IRIS assessments should take 26 months and complex assessments 39 months to complete. And Ken Olden, the director of EPA's National Center for Environmental Assessment, which oversees the IRIS program, has indicated at public meetings that he believes assessments will proceed more efficiently if potential areas of disagreement on the scope of assessments are discussed early in the process (*Risk Policy Report*, Sept. 25).

The first public meeting to discuss preliminary staff work on IRIS assessments will focus on three chemicals, two of which have been the subject of previous controversial agency assessment efforts. The Oct. 23-24 meeting, where EPA says it will provide "preliminary materials" for each chemical prior to the meeting, is scheduled to discuss tert-butyl alcohol (tert-butanol), ethyl-tert-butyl ether (ETBE), and hexahydro-1,3,5-trinitro-1,3,5-triazine, better known as royal demolition explosive (RDX), according to an Aug. 9 *Federal Register* notice. *Relevant documents are available on InsideEPA.com.* (*Doc ID: 2443695*)

"These materials are being released for public viewing and comment prior to the public meeting on October 23-24, 2013, which will provide an opportunity for the IRIS Program to engage in early discussions (before the IRIS assessments have been prepared) with stakeholders and the public on data that may be used to identify health hazards and characterize exposure-response relationships," the notice says.

The agency posted the draft literature search, the search strategy and preliminary tables of the results of the data for ETBE and tert-butanol on its website Aug. 12. The documents for RDX have yet to be posted; the website states they will be posted "approximately 60 days before the meeting."

The documents suggest EPA is re-starting its assessments of ETBE and RDX, each of which have long been mired in controversy. The ETBE assessment was one of five IRIS assessments that former research chief Paul Anastas stalled or reviewed in June 2010 because they referenced data from the controversial Italian laboratory known as the Ramazzini Institute. Industry and other critics argued that the Ramazzini labs' unorthodox methods overestimated the chemicals' cancer risks, and that as a result, EPA should not base its toxicity estimates upon its data.

EPA announced last year that it would not use Ramazzini cancer data in the ongoing IRIS assessments of methanol and the fuel additives methyl tertiary butyl ether (MTBE) and ETBE, suggesting re-writes of those documents would be necessary. Since then, EPA has released a draft IRIS assessment of methanol's non-cancer risks, but its methanol cancer assessment is listed as status "to be determined" on EPA's IRIS Track website, along with the MTBE assessment.

The documents that EPA provides on its website about ETBE include preliminary evidence tables summarizing the toxicity data EPA has reviewed. Literature searches for ETBE were conducted last January, resulting in 758 citations, of which 52 "were identified as primary sources of health effects data," the documents say. The resulting evidence tables show doses resulting in effects in lab animals ranging from kidney weight changes to kidney disease, liver weight, changes in liver enzymes, reproductive effects, weight loss and cancer. The evidence tables for cancer include one of the Ramazzini studies by Maltoni et al., published in the *European Journal of Oncology* in 1999.

While EPA decided after a lengthy pathology review of Ramazzini's data by National Toxicology Program scientists not to use the cancer data in its MTBE and ETBE assessments, the agency has suggested that it would continue to use Ramazzini data in other assessments where the agency's review generally agreed with the lab's results, such as in the existing assessment for vinyl chloride.

The RDX assessment was one of a series of IRIS assessments highlighted in a critical 2008 Government Accountability Office report that raised concerns about the amount of time it takes to complete the assessments. The chemical is an explosive the Defense Department (DOD) uses in thousands of munitions, and while its acute seizure hazards are known, the effects of chronic, low-level exposure are not. "Although EPA started an IRIS assessment of [RDX] in 2000, it has made minimal progress on the assessment because EPA agreed to a request by DOD to wait for the results of DOD-sponsored research on this chemical," according to the GAO report. "In 2007, EPA began to actively work on this assessment, although some of the DOD-sponsored research is still outstanding."

EPA's published, 1993 IRIS assessment classifies the chemical as a "possible human carcinogen." The GAO report notes that it "is known to leach from soil to groundwater," and that "the IRIS assessment could potentially require DOD to undertake a number of actions, including steps to protect its employees from the effects of this chemical and to clean up many contaminated sites."

Tert-butanol appears to be a new addition to the IRIS database, a chemical with numerous uses, including as a denaturant for ethanol, in the manufacture of flotation agents, flavors and perfumes, as a solvent, as an octane booster in gasoline as well as its use as a dehydrating agent, according to the U.S. National Library of Medicine's PubChem Compound website. Additionally, tert-butanol "is also a likely degradation product of . . . MTBE and has been detected in MTBE contaminated wells," the site states.

Like those for ETBE, the tert-butanol documents posted on EPA's website include preliminary evidence tables summarizing the toxicity data EPA has reviewed. Literature searches for ETBE were conducted last December and January, resulting in 2,410 unique citations, of which 106 "were identified as primary sources of health effects data," the documents say. The resulting evidence tables show doses resulting in effects in lab animals ranging from kidney weight changes to kidney disease, as well as thyroid, reproductive, developmental and central nervous system effects. -- *Maria Hegstad*

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